

IN THE CLAIMS:

This listing of claims below will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1. (Original) A method of providing demographic and clinical effectiveness and safety databases obtained from single-patient drug trials comprising a) conducting single-patient, cross-over drug trials of a drug and a placebo in a pool of individual human patients who are candidates for chronic treatment with said drug and obtaining samples of biological materials from the individual human patients before or during their single-patient drug trial; b) identifying genomic and gene expression markers in said pool of individual human patients by testing said biological materials using human DNA microarrays and Single Nucleotide Polymorphism and proteomic and successor technologies and assembling a patient population database of the markers from the pool of individual human patients; c) conducting a single-patient, cross-over drug trial of the drug and the placebo in a new individual human patient who is a candidate for chronic treatment with the drug and obtaining samples of biological materials from the new patient before or during that patient's single-patient drug trial; d) identifying in the new individual human patient genomic and gene expression markers by testing the biological materials using human DNA microarrays and Single Nucleotide Polymorphism and proteomic and successor technologies; e) comparing results from the human DNA and Single Nucleotide Polymorphism and proteomic and successor technologies testing accumulated from the pool of individual human patients with the human DNA and Single Nucleotide Polymorphism and proteomic and successor technologies testing from the new individual human patient to identify correlations between the results from the new individual human patient and the patient population database.

Claim 2. (Original) The method of claim 1, further comprising assembling said patient population database from a plurality of cross-over single patient drug trials prior to conducting step a.

Claim 3. (Original) The method of claim 2, further comprising adding the results from the single patient drug trial of the individual human patient to the patient population database.

Claim 4. (Original) The method of claim 2, further comprising accumulating the information of step (b) via the use of objective testing methodologies selected from the group consisting of mood, sedation, respiratory rate, pupil size and any combinations of the foregoing, which are measured by a visual analog scale.

Claim 5. (Original) The method of claim 2, further comprising prescribing said drug for chronic therapy in said patient.

Claim 6. (Original) The method of claim 2, wherein said single-patient clinical trials are conducted in an double-blinded fashion.

Claim 7. (Original) The method of claim 2, wherein said patient population database is stored on a computer.

Claim 8. (Original) The method of claim 7, wherein said computer database is accessible from a remote location.

Claim 9. (Original) The method according to claim 1, wherein said drug is selected from the group consisting of a drug for treating hyperkinetic behavior, an anti-asthmatic drug, an anti-epileptic drug, a cardiovascular drug, a respiratory drug, an antihypertensive drug, a steroidal anti-inflammatory drug, a non-steroidal anti-inflammatory drug, an opioid analgesic, a non-narcotic analgesic, a hematologic drug, a musculoskeletal drug, a gastro-intestinal drug, an anti-allergy drug, an anti-depressant drug, an anti-anxiety drug, an anti-psychotic drug, an antihistamine, a drug for the treatment of alzheimer's disease, a drug for the treatment of metabolic and/or endocrine disorders, a weight reduction agent, a drug for the treatment renal disease, a drug for the treatment central nervous system disorders, and a steroid.

Claim 10. (Withdrawn) The method according to claim 10, wherein said drug for treating hyperkinetic behavior is methylphenidate.

Claim 11. (Withdrawn) The method according to claim 10, wherein said cardiovascular drug is verapamil.

Claim 12. (Withdrawn) The method according to claim 10, wherein said cardiovascular drug is propranolol.

Claim 13. (Withdrawn) The method according to claim 10, wherein said steroid is an androgen-containing agent.

Claim 14. (Withdrawn) The method according to claim 10, wherein said steroid is an estrogen-containing agent.

Claim 15. (Original) The method according to claim 1, wherein said genomic and gene expression markers comprise surrogate markers of disease etiology and prognosis; drug effectiveness and safety; and lifestyle and intervention synergies.

Claim 16. (Original) The method of claim 1, wherein said single-patient, crossover drug trial comprises a test kit containing a supply of said drug; a supply of said placebo; and a questionnaire designed to elicit from said patient population information concerning the actual usage, safety, effectiveness and desirability of said drug.

Claim 17. (Original) The method according to claim 1, wherein said biological material is tissue.

Claim 18. (Original) The method according to claim 18, wherein said tissue is selected from the group consisting of intracellular tissue and extracellular tissue.

Claim 19. (Original) The method according to claim 1, wherein said biological material is a fluid.

Claim 20. (Original) The method according to claim 20, wherein said fluid is selected from the group consisting of blood, cerebral spinal fluid, amniotic fluid, bone marrow, visceral fluid, reproductive fluid, and excretory fluid.